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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/772,220	02/04/2004	LeNoir E. Zaiser	2173.2006-001	2185
21005	7590	02/27/2007	EXAMINER	
HAMILTON, BROOK, SMITH & REYNOLDS, P.C. 530 VIRGINIA ROAD P.O. BOX 9133 CONCORD, MA 01742-9133			BRANDT, ADAM CURTIS	
		ART UNIT		PAPER NUMBER
				3771
SHORTENED STATUTORY PERIOD OF RESPONSE		MAIL DATE	DELIVERY MODE	
3 MONTHS		02/27/2007	PAPER	

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/772,220	ZAISER ET AL.	
	Examiner	Art Unit	
	Adam Brandt	3771	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 04 February 2004.
 2a) This action is FINAL. 2b) This action is non-final.
 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-38 is/are pending in the application.
 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
 5) Claim(s) _____ is/are allowed.
 6) Claim(s) 1-38 is/are rejected.
 7) Claim(s) _____ is/are objected to.
 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date: _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>04/04/2005</u> | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Information Disclosure Statement

1. This office acknowledges receipt of the following items from the applicant: Information Disclosure Statement (IDS) filed 04/04/2005. The references cited on the PTOL 1449 form have been considered.

Priority

2. The examiner acknowledges the priority claimed under 35 U.S.C. §119(e) to U.S. Provisional Patent Application No. 60/444,995 filed on 02/04/2003.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.
4. Claims 11, 12, 17, 18, 29, 30, 36 and 37 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

As to claims 11, 17, 29 and 36, the Applicant recites a ratio of “45:1” in the claims but does not clearly establish to what the ratio applies. It is unclear if ratio applies the diameters of the nozzles, surface area of the nozzles, or the energy efficiency of the nozzles or solenoid. Claims 12, 18, 30 and 37 are rejected because they are dependent on a claim that is not clear and was thus rejected.

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

6. Claims 1-3, 5, 6 are rejected under 35 U.S.C. 102(b) as being anticipated by Evans (US 6,427,967).

As to claim 1, Evans discloses a gas regulator comprising a slave valve assembly (1,1a,1b) for receiving and controlling the flow of gas to a desired destination (gas received through 5 and delivered through 6); a timing chamber (10) positioned adjacent to the slave valve assembly, the timing chamber having an inlet for also receiving the gas (8); an electronically operated pilot valve assembly (9; column 6, lines 55-57) in communication with the timing chamber for operating the slave valve assembly, when the pilot valve assembly is closed, gas pressure within the timing chamber acting on the slave valve assembly closes the slave valve assembly (column 5, lines 27-37), and when the pilot valve assembly is open, gas exits the timing chamber reducing the gas pressure in the timing chamber thereby allowing the slave valve assembly to open and deliver the gas to the desired destination (column 5, lines 43-48).

As to claim 2, Evans discloses the slave valve assembly comprises a slave valve nozzle (opening that is occluded by 1b) and a slave valve member (1,1a,1b) for engaging the slave valve

nozzle, the gas pressure within the timing chamber acting on the slave valve member controlling the operation of the slave valve member.

As to claim 3, Evans discloses in column 3, lines 19-29, the slave valve member is a diaphragm.

As to claim 5, Evans discloses in column 6, lines 55-57, the electronically operated pilot valve assembly is a solenoid operated pilot valve assembly.

As to claim 6, Evans discloses the solenoid operated pilot valve assembly comprises a pilot valve nozzle (inlet to housing 32 and exit to housing towards drain 33), a pilot valve member for engaging the pilot valve nozzle (9), and a solenoid for operating the pilot valve member (column 6, lines 55-57).

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

8. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

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1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

9. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

10. Claims 4 and 23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Evans (US 6,427,967) in view of Shirai et al. (US 4,738,283).

As to claim 4, Evans substantially discloses the gas regulator with an electronically operated pilot valve, but does not specifically recite that the pilot valve assembly includes a piezoelectric device. Shirai et al. teaches that a pilot valve with a piezoelectric device is well known through the use of an example found on column 2, lines 13-19. Therefore, it would have been obvious to one of ordinary skill in the art to modify Evans gas regulator with the piezoelectric igniter as taught by Shirai et al. in order to have an alternate and reusable source of energy to power the solenoid.

As to claims 23, the modified device of Evans discloses the structure of the gas regulator detailed in the claims above. Therefore, the method steps would have been obvious because they would have resulted from the use of the modified device of Evans.

11. Claims 7-13, 15-18 and 26-37 are rejected under 35 U.S.C. 103(a) as being unpatentable over Evans (US 6,427,967) in view of Smith et al. (4,789,143).

As to claim 7, Evans substantially discloses the gas regulator, but fails to disclose the pilot valve assembly further comprises a spring for biasing the pilot valve member towards the pilot valve nozzle to be normally closed. Smith et al. teaches a rotary spring biased valve used in a flow control valve (column 7, lines 37-39 and column 8, lines 13-18). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify Evans gas regulator with a spring biased rotary valve as taught by Smith et al. in order to ensure that if the solenoid was to fail, it would fail in the closed position.

As to claim 8 and 16, Evans discloses the pilot valve nozzle and pilot valve members are aligned along a common axis (both are aligned along the length of the nozzle), whereby the pilot valve member moves along the axis for engaging and disengaging from the pilot valve nozzle (pilot valve member rotates about axis to engage and disengage the nozzle).

As to claim 9, Evans discloses the slave valve assembly, the timing chamber and the solenoid operated pilot valve assembly are positioned within a common housing (2,3), the timing chamber and the pilot valve nozzle being connected by a passage therebetween (8).

As to claim 10, Evans discloses the slave and pilot valve nozzles each have an opening, but does not specifically recite the pilot valve nozzle opening being smaller than the slave valve nozzle opening for the purpose of minimizing the solenoid size and energy expended by the

solenoid. It would have been obvious matter of design choice to reduce the pilot valve nozzle opening to smaller than that of the slave valve nozzle opening, since such a modification would have involved a mere change in the size of a component. A change in size is generally recognized as being within the level of ordinary skill in the art. *In re Rose*, 105 USPQ 237 (CCPA 1955).

As to claim 11, 12, 17 and 18, Evans does not disclose the slave valve nozzle has a 45:1 ratio to the pilot valve nozzle and that the slave valve nozzle opening is .048 inches and the pilot valve nozzle opening is about .007 inches in diameter. The valve assembly disclosed by Evans can be machined in order to meet any reasonable tolerances expected for usual operation. It would have been obvious matter of design choice to have specific size characteristics of the valve nozzles that optimizes the performance of the valve system, since such a modification would have involved a mere change in the size of a component. A change in size is generally recognized as being within the level of ordinary skill in the art. *In re Rose*, 105 USPQ 237 (CCPA 1955).

As to claim 13, Evans does not specifically recite the gas being controlled by the valve is oxygen, but it is obvious that any gas could be controlled in the valve system. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to use oxygen as the gas being controlled by the gas regulator for the purpose of using the gas regulator in an oxygen delivery system so that the patient does not suffer from hypoxaemia.

As to claim 15, Evans discloses a gas regulator comprising a housing (2,3); a slave valve assembly (1,1a,1b) positioned within the housing for receiving and controlling the flow of a gas to a patient (gas received through 5 and delivered through 6), the slave valve assembly having a slave valve nozzle (opening that is occluded by 1b) and a slave valve member (1,1a,1b) comprising a diaphragm (column 3, lines 19-29) for engaging the slave valve nozzle; a timing chamber (10) within the housing positioned within the housing adjacent to the slave valve member, the timing chamber having an inlet (8) for also receiving the oxygen; and a solenoid operated pilot valve assembly (9; column 6, lines 55-57) positioned within the housing and in communication with the timing chamber by a passage (9) therebetween for operating the slave valve assembly, the solenoid operated pilot valve assembly comprising a pilot valve nozzle (inlet to housing 32 and exit to housing towards drain 33), a pilot valve member (9), and when the pilot valve assembly is closed oxygen pressure within the timing chamber acting on the slave valve member closes the slave valve assembly (column 5, lines 27-37), and when the pilot valve assembly is open, oxygen exits from the timing chamber reducing the oxygen pressure in the timing chamber thereby allowing the slave valve assembly to open and deliver the gas to the patient (column 5, lines 43-48).

Evans does not specifically recite the gas being controlled by the valve is oxygen, but it is obvious that any gas could be controlled in the valve system. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to use oxygen as the gas being controlled by the gas regulator for the purpose of using the gas regulator in an oxygen delivery system so that the patient does not suffer from hypoxaemia.

Evans substantially discloses the gas regulator, but fails to disclose the pilot valve assembly further comprises a spring for biasing the pilot valve member towards the pilot valve

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nozzle to be normally closed. Smith et al. teaches a rotary spring biased valve used in a flow control valve (column 7, lines 37-39 and column 8, lines 13-18). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify Evans gas regulator with a spring biased rotary valve as taught by Smith et al. in order to ensure that if the solenoid was to fail, it would fail in the closed position.

Evans discloses the slave and pilot valve nozzles each have an opening, but does not specifically recite the pilot valve nozzle opening being smaller than the slave valve nozzle opening for the purpose of minimizing the solenoid size and energy expended by the solenoid. It would have been obvious matter of design choice to reduce the pilot valve nozzle opening to smaller than that of the slave valve nozzle opening, since such a modification would have involved a mere change in the size of a component. A change in size is generally recognized as being within the level of ordinary skill in the art. *In re Rose*, 105 USPQ 237 (CCPA 1955).

As to claims 26-37, the modified device of Evans discloses the structure of the gas regulator detailed in the claims above. Therefore, the method steps would have been obvious because they would have resulted from the use of the modified device of Evans.

12. Claims 20-22, 24 and 25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Evans (6,427,967).

As to claims 20-22, 24 and 25, Evans discloses the structure of the gas regulator detailed in the claims above. Therefore, the method steps would have been obvious because they would have resulted from the use of the device of Evans.

13. Claims 14, 19 and 38 are rejected under 35 U.S.C. 103(a) as being unpatentable over as applied to Evans (US 6,427,967) in view of Smith et al. (4,789,143) in claim 13 above, and further in view of Piper et al. (US 5,479,920).

As to claim 14 and 19, the modified device of Evans does not disclose a sensing circuit for sensing inhalation by the patient for controlling the electronically operated pilot valve assembly. Piper et al. teaches in column 6, lines 4-11, a sensing circuit that measures the change in pressure a patient's breathing cycles and actuates a solenoid in correspondence to ease the hardship of breathing. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify Evans gas regulator with the breath sensing circuit of Piper et al. in order to automate solenoid activation for an application where repeated operation occurs.

As to claim 38, the modified device of Evans discloses the structure of the gas regulator detailed in the claims above. Therefore, the method steps would have been obvious because they would have resulted from the use of the modified device of Evans.

Conclusion

14. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Valdespino et al. (4,736,750); Snook et al (4,932,402); Reynolds (6,036,445); O'Neil (6,170,526); Bushik et al. (6,793,199) all relate to ventilators, sensing circuits, piezoelectrics, or solenoid valves.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Adam Brandt whose telephone number is 571-272-7199. The examiner can normally be reached on 8:30 AM to 4:30 PM; Mon thru Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Justine Yu can be reached on 571-272-4835. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

ACB
ACB


Adam Brandt
Examiner
Art Unit 3771


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SUPERVISORY PATENT EXAMINER
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2/26/07